DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

October 26, 2001

WL-11-02

Eric A. Crespal, President
French Delices, Inc.
7333 Fulton Avenue
North Hollywood, CA 91605

Dear Mr. Crespal:

We inspected your firm, located at the above address on September 25 and 26, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your cold smoked fishery products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for cold-smoked salmon to control the food safety hazards of *Clostridium botulinum* growth and toxin formation. We note that your cold-smoked salmon is vacuum-packaged and is then held under refrigeration.

   According to 21 CFR 123.16, processors of smoked and smoke-flavored fishery products shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf-life of the product.

2. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm could not provide any HACCP monitoring records for the storage between September 19th-25th, 2001. Please note that your apparent critical control point monitoring record we observed does not conform with the formal record requirements of 21 CFR 123.9, nor is it the record identified in your HACCP plan for scombrotoxin-forming species to record this type of monitoring data; e.g., "Time/Temp. log." This record appears to be a wall calendar.

Your lack of monitoring for the refrigerated storage critical control point was also brought to your attention during the February 18-23, 2000 inspection of your facility by FDA; this deficiency was also part of a HACCP letter sent to your firm (Ref. U/L 00-50 dated July 6, 2000).

3. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, you have not had any sanitation control records since May 2001.

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the required areas of sanitation with sufficient frequency to ensure control, as evidenced by sanitation deficiencies found during our inspection. These deficiencies included the observation that the slicing machine used to slice post-process (cold-smoked) salmon had an accumulation of salmon residue on this cutting machine. This material appeared to have been present due to a lack of, or improper, equipment cleaning.

The above-cited violations are not intended to be an all-inclusive statement of the deficiencies that may exist with your processing operation. It is your responsibility to assure that all of your fishery products are processed in compliance with the requirements of the Act, Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110) as appropriate. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. You may wish to include in your response documentation such as HACCP plans, monitoring forms, and recent monitoring data or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be addressed to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director